Early supported discharge after stroke in Bergen (ESD Stroke Bergen): a randomized controlled trial comparing rehabilitation in a day unit or in the patients' homes with conventional treatment

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Rationale **As a result of demographic changes with a presumed rapidly increasing number of older people during the coming decades, a strong increase in the incidence and prevalence of stroke should be expected. Early supported discharge implies that the patients are discharged to their homes as soon as feasible and that rehabilitative treatment is offered after the discharge, with the patients being home-dwelling. This has proved beneficial in previous studies.**

Aims **The main objective of this study is to further characterize the important components of early supported discharge and to confirm superiority of early supported discharge over conventional treatment. The secondary aim will be to compare two different early supported discharge schemes. These early supported discharge schemes are composed of intensive rehabilitation treatment given by a multidisciplinary team in a day unit and, alternatively, the same treatment given in the patients' homes.**

Design **The study is conducted as a randomized controlled trial with three arms: two different forms of early supported discharge and a control arm with conventional treatment. Patients with acute stroke admitted to our hospital's stroke unit and living in the Municipality of Bergen are considered for inclusion. A total of 350 stroke patients are expected.**

Study outcomes **Primary outcome is modified Rankin Scale six-months after inclusion. Secondary outcomes include Barthel Index and National Institute of Health Stroke Scale at several points in time after inclusion, as well as many other schemes, questionnaires and physical tests. The study is registered in *ClinicalTrials.gov* registration number NCT00771771.**

Key words: clinical trial, early supported discharge, ESD, RCT, rehabilitation, stroke

Introduction

The number of strokes in Norway is estimated to approximately 14 500 per year (1). Stroke is the third most common cause of death in our country and the most common cause of lasting disability (1), and it consumes a substantial part of our health-care resources. The best possible outcome after stroke is therefore essential, both for the individual patient and for the society. Several studies have indicated that an early supported discharge (ESD) model for stroke patients is better than hospital rehabilitation (2–7). A Cochrane report from 2005, evaluating the available published studies until then, concluded that ESD was beneficial for a selected group of stroke patients (8). A consensus document has recently been created, with statements regarding team composition, model of teamwork, intervention, and success (9).

However, the original Cochrane report emphasized the need for future studies in order to clarify which elements of ESD in the primary health care were important, and for more precise clarification of cost–benefit in different patient groups. A recent meta-analysis reviewed the results from 11 trials where rehabilitation was offered either centre-based or home-based and found a significant effect in favor of home-based rehabilitation at six-weeks and three- to six-months (10). This question is also addressed in the present study. The main objective of the study is to further characterize the important components of ESD and to confirm superiority of ESD over conventional treatment. The secondary aim will be to compare the two different ESD schemes.

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Methods

Design

The main hypotheses are that treatment with ESD is superior to ordinary rehabilitation in hospital and that the more precise composition of the treatment during the first intensive phase after discharge from hospital may be of importance. We have therefore established two different treatment modalities where the difference is the treatment arena: it is given either in a day unit or in the patients' own homes. Also, the amount and intensity of rehabilitation and follow-up after early discharge is important for the degree of benefit from the treatment, and this is therefore as far as possible kept at the same level in the two treatment modalities.

The study is conducted as a three-armed randomized controlled trial. Patients in the study arms A and B are treated with ESD according to the two different outpatient follow-up schemes. Patients in arm C receive treatment after today's principles and they thereby constitute a control group. A schematic overview of the study and patient flow is given in Fig. 1.

Patient population

All stroke patients living in Bergen admitted to the Department of Neurology, Haukeland University Hospital, are considered for inclusion in the study. The inclusion and exclusion criteria are shown in Table 1. The inclusion period is 8 December 2008 through 20 December 2011, except for Easter, summer, and Christmas holiday periods.

Randomization

The patients are prerandomized into three groups (A, B, and C) by computer-generated block randomization with six patients in each block. The consecutive patients are assigned to their group in the same order as they are included into the study. The randomization group is not known to the patients nor the persons testing them at baseline, and as far as possible, not to the testers later in the study. These testers are partly other persons than in the acute phase testing, and the patients are instructed not to tell their group to the testers.

Treatment/intervention

Treatment in arms A and B

The treatment is given in accordance with the ESD concept, which in this study encompasses the following:

- The patients are discharged to their homes as early as possible and advisable. Generally, this means that the patients should be capable of independent locomotion and to go to the

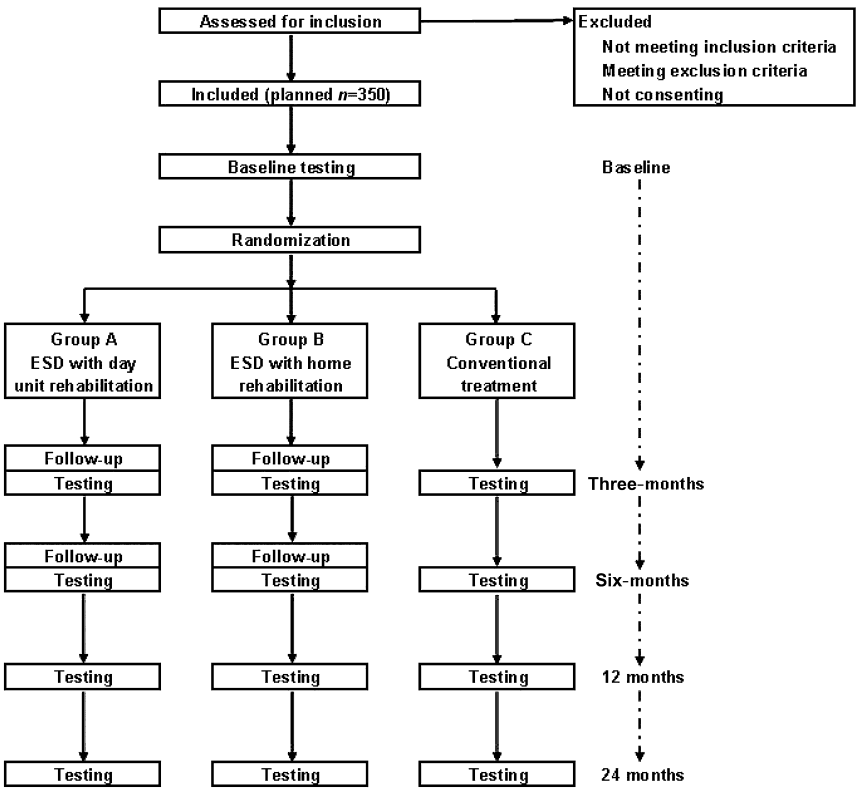

Fig. 1 Overview of study and patient flow.

Table 1 Inclusion and exclusion criteria

Inclusion criteria are:
Patient must be home-dwelling and live in the Municipality of Bergen
Inclusion within one- to seven-days after symptom onset
Inclusion within six-hours to 120 h after admission to the Department of Neurology
NIHSS score at inclusion 2–26, or a two-point increase in mRS score if 0 or 1 previously
Patients must be awake and be able to agree to the participation in the study by themselves or by relatives
No age limit for inclusion.
Exclusion criteria are:
Serious psychiatric disorders
Alcohol or substance abuse
Other serious conditions of importance to the cerebral disorder and subsequent rehabilitation process
Poor knowledge of the Norwegian language before the stroke.

toilet without help. The more affected patients therefore may need an inpatient rehabilitation period before discharge to home.

• During the hospitalization and the first five-weeks after discharge, the patients are followed and supervised by an outpatient ambulatory coordinating team, including physiotherapist, occupational therapist, and nurse. This team cooperates closely with the municipal health care in the planning and implementation of further rehabilitation after discharge. The ambulatory team has a central coordinating function and serves as a link between the patient, relatives, hospital personnel, and the personnel in the municipal health care. The ambulatory team connects with the individual patients as well as the municipal health care as soon as possible after randomization to study arm. The team members participate in transfers between the health-care levels, and they participate in home visits and the later multidisciplinary outpatient follow-ups at the Department of Physical Medicine and Rehabilitation.

• The patients are offered treatment by a specific municipal health-care team up to four-hours a day for up to five-weeks after discharge from hospital. This team is composed of physiotherapists, occupational therapists, and a nurse trained for stroke patients. Treatment by other professions, particularly speech therapists, is considered if needed. It is considered important that the municipal health-care team's treatment is comparable with the rehabilitation otherwise offered at an inpatient department but remaining day-based with the patients living in their own homes. The amount of rehabilitation given in this five-week period is modified according to the patients' needs and recorded as treatment hours with each of the team's professions.

• Systematic multidisciplinary outpatient follow-ups are offered three- and six-months after inclusion. The main intention with this follow-up is to discover the various needs that the patients may have and then provide necessary help or report this information to the municipal health care. In addition, lifestyle issues including physical activity are discussed when appropriate.

Particulars for treatment arm A

These patients receive the treatment from the municipal health-care team in a day unit.

Particulars for treatment arm B

These patients receive the treatment from the municipal health-care team in their own homes.

Treatment in arm C (the control group)

The stroke patients in this group receive treatment after today's principles and routines. This encompasses acute stroke treatment in a stroke unit, followed by transfer to the Department of Physical Medicine and Rehabilitation, if needed, based on a professional judgment. Other alternatives are discharge directly to home or discharge to inpatient treatment in a municipal health care institution.

Primary outcome

The primary outcome in this study is the modified Rankin Scale (mRS) value six-months after inclusion.

Secondary outcomes

In addition, the patients included in the study will be evaluated with many other predefined measuring instruments zero-, three-, six-, 12, and 24 months after inclusion. All the outcomes (primary and secondary) are listed in Table 2.

At baseline mRS, Barthel Index (BI) and National Institute of Health Stroke Scale (NIHSS) are administered by stroke neurologists or trained stroke nurses in the Stroke unit. At three-, six-, and 12 months, the scales are administered to all patients by one single person (physiotherapist) who was initially trained by an experienced stroke nurse. Generally, 30–45 mins are allocated to these scorings after the acute phase, with additional information acquired from relatives or other health workers when appropriate. MRS and BI at 24 months are scored based on telephone interview.

Table 2 Primary and secondary outcomes

Time	Registrations and questionnaires
Before or at inclusion	E-stroke[†], NIHSS[‡]
Soon after inclusion	AMPS[§], TIS[¶], PASS**, TUG[††], FAC[‡‡], NRS[§§], MMSE[¶¶]
	Standardized five-meter walking test
	Evaluation by speech therapist*
Seven-days after inclusion or earlier if discharged from the stroke unit	NIHSS, mRS***, BI[†††]
	Comorbidity questionnaires (SCQ[‡‡‡], SHC[§§§])
Three-months after inclusion	NIHSS, mRS, BI, Patient satisfaction
	AMPS, TIS, PASS, TUG, FAC, NRS
	Standardized five-meter walking test
	Evaluation by speech therapist*
Six-months after inclusion	NIHSS, mRS, BI, patient satisfaction
	AMPS, TIS, PASS, TUG, FAC, NRS
	Standardized five-meter walking test
12 months after inclusion	NIHSS, mRS, BI, SIS[¶¶¶], RSS****, PGIC[††††], SF-36[‡‡‡‡] Patient satisfaction
	Cognitive/neuropsychological evaluation
	Evaluation by speech therapist*
24 months after inclusion	mRS, BI, PGIC, SF-36

All patients included in the study are systematically evaluated at predefined points in time after inclusion and with predefined measuring instruments as follows (*only in patients with pathological findings at the initial examination).
Function schemes: National Institute of Health Stroke Scale, Functional Ambulation Categories, modified Rankin Scale, Barthel ADL Index.
Objective tests: Assessment of Motor and Process Skills, Trunk Impairment Scale, Postural Assessment Scale for Stroke, Timed Up-and-Go, Mini-Mental State Examination, Standardized five-meter walking test.
Other questionnaires: Numeric Rating Scale, Self-Administered Comorbidity Questionnaire, Subjective Health Complaints, Patient satisfaction, Stroke Impact Scale, Relative Stress Scale, Patient Global Impression of Change, Short Form 36 Health Survey.
[†]E-stroke (Bergen NORSTROKE Registry) is a systematic registration of many different variables at admittance/inclusion and through the acute phase, including both demographic variables and variables directly related to the patients' stroke disease. Magnetic resonance imaging is performed on most patients, CT scan on the others. Electrocardiography (ECG), 24-h ECG, and ultrasound examination of heart and neck vessels are included.
[‡]National Institute of Health Stroke Scale: a systematic assessment tool that provides a quantitative measure of stroke-related neurologic deficit; in this study, a version with maximum score 34 is used, which evaluates motor function only on affected side.
[§]Assessment of Motor and Process Skills: an observational assessment that is used to measure the quality of a person's activities of daily living (ADL) by rating the effort, efficiency, safety, and independence of motor and process skill items while the person is doing chosen and familiar ADL tasks.
[¶]Trunk Impairment Scale: evaluates the patients' level of trunk control poststroke and was originally developed for the stroke population.
**Postural Assessment Scale for Stroke: evaluates the patient's postural control at the activity dimension of the ICF (International Classification of Functioning, Disability and Health).
[††]Timed Up-and-Go: the patient is required to rise from a chair, walk three-meters, turn, walk back to the chair, and sit down; time is measured for the whole sequence.
[‡‡]Functional Ambulation Categories: categorizes the patient's walking ability in relation to six levels of physical support.
[§§]Numeric Rating Scale: 11 levels from 0–10, used to detect the patient's own perception of stroke-related problems with walking, balance, coping with ADL, safety in physical activity, pain, and fatigue.
[¶¶]Mini-Mental State Examination: a brief 30-point questionnaire test used to screen for cognitive impairment.
***Modified Rankin Scale: evaluates the patient's ADL function in seven levels; levels 0–2 signify independence.
[†††]Barthel ADL Index: examines the patient's ADL function using 10 variables describing ADL and mobility.
[‡‡‡]Self-Administered Comorbidity Questionnaire: a self-administered measure of comorbidity, also allowing the patient to note the severity of each comorbid condition and his or her perception of its impact on function.
[§§§]Subjective Health Complaints: composed of 29 questions concerning severity and duration of subjective somatic and psychological complaints.
[¶¶¶]Stroke Impact Scale: assesses health status following stroke in eight different domains: strength, hand function, ADL/instrumental ADL, mobility, communication, emotion, memory and thinking and participation/role function.
****Relative Stress Scale: a 15-item interviewer-administered questionnaire designed to measure the reaction to caregiving of relative carers of elderly patients living in the community; originally developed for dementia.
[††††]Patient Global Impression of Change: addresses self-reported change in the severity of a patient's illness over a particular time interval; in the present context since start of treatment after stroke.
[‡‡‡‡]Short Form 36 Health Survey: a multipurpose, short-form health survey with 36 questions constructed to satisfy minimum psychometric standards necessary for group comparisons.
Standardized five-meter walking test: the patient walks nine-meters at self-selected speed and time is taken during the middle five-meters.
Patient satisfaction: scores self-reported benefit of and satisfaction with treatment received after stroke in five levels.

Data management

All collected data are stored in specially allocated secure areas on the hospital's server, with the actual data and the patients' identity being kept apart in different server areas.

Sample size

A sample size of approximately 350 included acute stroke patients is expected within the three-year inclusion period. These are divided into two active treatment groups and a control group, each of 117 patients. Based on a previous relevant study of acute stroke patients (7), the expected proportions of patients with mRS ≤ 2 at six-months are calculated to 57·9 % for the treatment groups and 40·2 % for the control group. This provides a power of 74 % to demonstrate a statistically significant difference between the groups for the main outcome mRS.

Statistical analyses

Differences between and within the groups at the follow-up time points will be tested. Number needed to treat to obtain one more independent stroke patient in the intervention groups vs. the control group will be calculated. Analysis of variance (ANOVA) and analysis of covariance analyses (ANCOVA) will be used to measure average differences between and within the treatment groups at different points in time. Logistic regression will be performed to estimate odds ratio and relative risk. Intention to treat and per-protocol analyses will be used.

In a longitudinal design treatment effect based on measurements at several points in time will be estimated using methods for repeated and correlated observations such as general estimation equations to correctly estimate confidence intervals and *P*-values.

Various subgroup analyses will be performed, including analyses according to the patients' stroke severity evaluated by initial NIHSS score.

Health economics

Treatment cost will be calculated for each of the three treatment arms. The three alternatives will thereafter be compared in a cost-effectiveness analysis in order to discover differences in cost-effectiveness between the different treatment arms (11).

Organizational studies

The project's organizational studies are closely coupled with the design of the study and focusing on organizational changes. The analytical approach centers on combining multilevel approaches with standard theoretical premises for organizational behavior, gathered from instrumental, strategic, and institutional theories, in order to create a framework for interpreting and understanding the organizational processes involved with the planning and implementation of the stroke rehabilitation chain. This enables identification of varying types of organizational barriers against change, exposing limitations of the social structures involved with stroke treatment – but also an approach to evaluate the rehabilitation chain in organizational terms. The Uni Stein Rokkan Centre for Social Studies will undertake this part of the study.

Study organization

The study is conducted in collaboration between Haukeland University Hospital (Department of Physical Medicine and Rehabilitation, Department of Neurology and the Medical Service Department), the Municipality of Bergen and University of Bergen, Bergen, Norway (Department of Public Health and Primary Health Care). University of Bergen is project owner and research responsible institution, and Haukeland University Hospital carries the responsibility for medical treatment, clinical registrations, and data collection.

Discussion

ESD after stroke has been shown to be beneficial in previous models reported from various Western countries. Why this model works and which components that are crucial is, however, mostly unclear. Task-specific motor training promotes restorative neuroplastic changes (12). Living in a home environment during rehabilitation may therefore be optimal since this will promote practicing the essential tasks of daily living.

In this study, rehabilitative treatment given at home or in a day unit will be compared with ordinary care without use of the principles of ESD. In addition, rehabilitation given at home and in a day unit will be compared. This study also differs from previous studies in the way that the participants will be much more extensively tested at fixed points in time during the first 24 months after stroke and with a variety of tests including physical tests, various scoring schemes and questionnaires.

Results from previous studies indicate that patients with mild to moderate stroke severity benefit the most from ESD (8). In this study, the effect of the different treatment protocols will be evaluated in lightly, medium-, and more severely affected stroke patients. Also, treatment cost and total societal economic cost will be calculated for each of the treatment protocols, thereby providing important information for future planning of rehabilitation programs.

The study has been approved by the Western Norway Regional Committee for Medical Research Ethics.

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Municipal health-care team

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